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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|---------------------|------------------|
| 09/997,551 | 11/27/2001 | Jian-Dong Li | HOUSEEI.001A | 7280 |
| 20995 | 7590 | 10/06/2003 | EXAMINER | |
| KNOBBE MARTENS OLSON & BEAR LLP | | | SCHULTZ, JAMES | |
| 2040 MAIN STREET | | | ART UNIT | |
| FOURTEENTH FLOOR | | | PAPER NUMBER | |
| IRVINE, CA 92614 | | | 1635 | |

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,551

Applicant(s)

LI ET AL.

Examiner

J. Douglas Schultz

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4 are drawn to a method for treatment of overproduction of mucin in a mammal comprising administering any of pyridinyl imidazole SB203580, SB202190, SB220025, SC68376, or SKF-86002 to the mammal in an amount sufficient to reduce mucin production, classified in class 514, subclass 235.8.
- II. Claims 1-4 and 7, drawn to a method for treatment of overproduction of mucin in a mammal comprising administering a dominant-negative mutant of p38 α MAP kinase to the mammal in an amount sufficient to reduce mucin production, classified in class 514, subclass 2.
- III. Claims 1-4 and 7, drawn to a method for treatment of overproduction of mucin in a mammal comprising administering a dominant-negative mutant of p38 β MAP kinase to the mammal in an amount sufficient to reduce mucin production, classified in class 514, subclass 2.
- IV. Claims 1-3, 5 and 7, drawn to a method for treatment of overproduction of mucin in a mammal comprising administering an antisense molecule to p38 MAP kinase

to the mammal in an amount sufficient to reduce mucin production, classified in class 514, subclass 44.

- V. Claims 1-3, 6 and 7, drawn to a method for treatment of overproduction of mucin in a mammal comprising administering a vector expressing a p38 MAP kinase inhibitory protein to the mammal in an amount sufficient to reduce mucin production, classified in class 514, subclass 44.
- VI. Claims 8-12, drawn to a method of screening for regulators of mucin production, classified in class 435, subclass 6.
- VII. Claims 13-20, drawn to a method for treatment of overproduction of mucin in a mammal comprising administering a dominant negative mutant of PI-3 kinase to the mammal in an amount sufficient to reduce mucin production, classified in class 514, subclass 2.
- VIII. Claims 13-20, drawn to a method for treatment of overproduction of mucin in a mammal comprising administering a constitutively active form of p110 (p110-CAAX) to the mammal in an amount sufficient to reduce mucin production, classified in 514, subclass 2.

- IX. Claims 13-20, drawn to a method for treatment of overproduction of mucin in a mammal comprising administering wild-type Akt to the mammal in an amount sufficient to reduce mucin production, classified in class 544, subclass 2.
- X. Claims 13-20, drawn to a method for treatment of overproduction of mucin in a mammal comprising administering an antisense molecule to p38 MAP kinase to the mammal in an amount sufficient to reduce mucin production, classified in class 514, subclass 44.
- XI. Claims 13-20, drawn to a method for treatment of overproduction of mucin in a mammal comprising administering a vector expressing a protein that activates PI-3 kinase to the mammal in an amount sufficient to reduce mucin production, classified in class 514, subclass 44.

The inventions of all of groups I-V are unrelated to all of those of in Groups VII-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Groups I-V are drawn to methods requiring the administration of an inhibitor of p38 MAP kinase for correcting the overproduction of mucin, said p38 being a different target than that of that of groups VII-XI, which targets PI-3 kinase. Because the PI-3 kinase target of Groups VII-XI differ both structurally and functionally from the p38 MAP kinase target of Groups I-V, the search for inhibitors of the targets of Groups VII-

XI are different from that for Groups I-V, and are not co-extensive. In addition to being structurally different, the methods of modulating p38 MAP kinase of Groups I-V are not disclosed as capable of use with any of the methods of modulating PI-3 kinase of Groups VII-XI.

Furthermore each Group within Groups VII-XI recites modulation of a pathway related to mucin production wherein said modulation is achieved by inhibitors that differ structurally and functionally from each other, are not members of an art recognized class, and thus require different searches which are not co-extensive, because a search for art against one group would not reveal art against another group.

Similarly, each Group within Groups I-V recites modulation of a pathway related to mucin production wherein said modulation is achieved by inhibitors that differ structurally and functionally from each other, are not members of an art recognized class, and thus require different searches which are not co-extensive, because a search for art against one group would not reveal art against another group.

The methods of inhibiting p38 of Groups I-V and the methods inhibiting PI-3 kinase of Groups VII-XI are unrelated to the method of Group VI, which is drawn to a screening process involved in the identification of various potential inhibitors of p38 MAP kinase. The screening process requires administering molecules from a large library and determining what if any effects are had on p38 MAP kinase, which are steps unique to this group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Furthermore, because the searches are not co-extensive, and these inventions are independent or distinct for the reasons given above, to search of all these inventions in one application represents an undue burden on the Office due to the divergent subject matter and nature of searching. Thus, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD


KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER